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## Japan

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### Japan Takes Step Forward to Improve its Pesticide Review Process

**Report Categories:**

Export Accomplishments - Other

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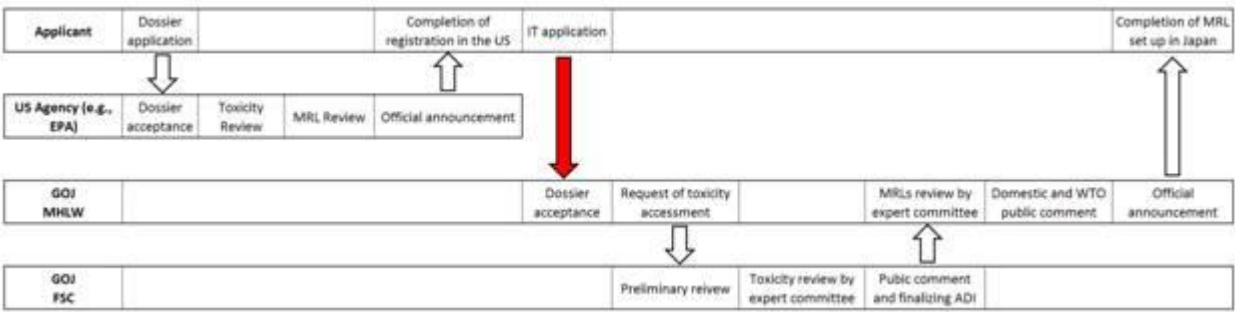
**Report Highlights:**

On May 14, 2013, Ministry of Health, Labor and Welfare (MHLW) of the Government of Japan (GOJ) announced that it would accept applications for Import Tolerances (IT) even if the maximum residue level (MRL) of the chemical is not finalized in the export country. MHLW's new system will allow import tolerance applications to start the review process 12 to 15 months earlier than in the previous system and will therefore minimize delays in the establishment of new MRLs. The real-time establishment of MRLs in Japan for new agrochemicals will allow U.S. agricultural exporters to minimize uncertainties in trade to Japan.

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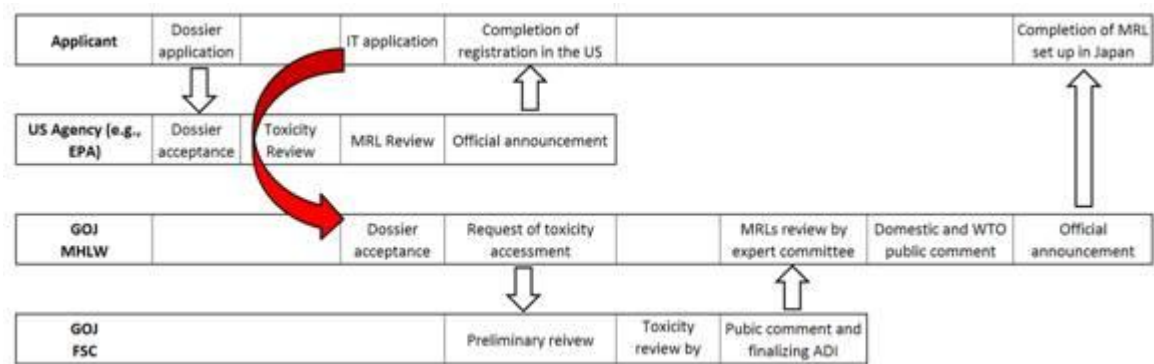
In the past, the Ministry of Health, Labor and Welfare (MHLW) accepted the application for import tolerances (IT) only after the MRL was officially finalized in the country where the substance would be used (Figure 1). Depending on the substance, Japan's review of new agrochemicals took 24 to 36 months to complete. As a result, there was a significant delay between the time an agrochemical was approved for use in the United States and when it was approved in Japan. Hence, U.S. growers exporting commodities to Japan were often unable to use the latest pest management technology in order to avoid being found in violation of Japanese import regulations. New substances are often safer, more effective and necessary for farmers to manage increasing pest pressure, chemical resistant weeds, pests and fungi. This time-lag between the registration in the original country (e.g., the United States) and the MRL establishment in an export market (e.g., Japan) has been extremely problematic for U.S. agricultural trade to Japan.

Figure 1.  
Japan's Previous MRL establishment and IT application scheme (before May 14, 2013)



However, on May 14, 2013, MHLW announced that it would accept IT applications even when the MRL of the chemical is not finalized in the applicant country (Figure 2, Attachment 1). Under this new scheme, MHLW will no longer require that the MRL in the export country be officially announced in order to submit an IT application in Japan. MHLW does require that the MRL in the export country be officially finalized by the time Japan's Food Safety Commission (FSC) returns the application dossier back to MHLW for MRL review. Although the timeframe varies significantly depending on the substance, it usually took a total of 12 months for MHLW to conduct its preliminary assessment and the FSC to complete its toxicity review. Now, under the new IT application scheme, the provider can start the application process with MHLW while the review of the agrochemical in the export country is still ongoing. Therefore, the new scheme promises to significantly reduce the duration of Japan's review process by as much as 12 to 15 months.

Figure 2.  
Japan's New MRL establishment and IT application scheme (after May 14, 2013)



## Ministry of Health, Labor and Welfare's Announcement on May 14, 2013

### **Item 3. Guideline for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used Outside Japan**

#### Summary

On February 5, 2004, the Ministry of Health, Labour and Welfare published the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan (Director-General Notice of the Department of Food Safety, Shokuan-No. 0205001, 5 February 2004). The MHLW has partially revised the requirements for application specified in the guideline.

#### Outline of revision

The MHLW sets MRLs (maximum residue limits) for agricultural chemicals in food based on the result of risk assessment by the Japan's Food Safety Commission (FSC).

Before the guideline was revised, only when there were MRLs set in the target commodities in the applicant country, the MHLW accepted an application for setting of import tolerances and asked the FSC to assess the risk of the target compound.

After the revision, even when MRLs have not yet been set in the target commodities in the applicant country, the MHLW accepts an application for setting of import tolerances and asks the FSC to conduct risk assessment on condition that MRLs will be set. However, import tolerances will be set when MRLs are set for the target commodities.

#### Attachment

Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals used outside Japan (Director-General Notice of the Department of Food Safety, Shokuan-No. 0205001, 5 February 2004).

## Attachment .

Original: Japanese  
Provisional Translation

### Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals used outside Japan

#### I . Purpose

This guideline outlines the procedures required to apply for the establishment and revision of maximum residue limits (MRLs) for agricultural chemicals on/in foods, and the scope of required documents. The guideline targets agricultural chemicals — pesticides, veterinary drugs, and feed additives — that are approved in the foreign countries for foods exported to Japan. The foods include agricultural products, animal products, or seafood.

The requirements given in this document notwithstanding, it is not necessarily appropriate to require a uniform set of documents for every chemical. Also, advances in science and technology may bring new analytical and evaluation methods. Therefore, the study results and related documents given in the guideline can be replaced by other documents sufficient to conduct evaluation for establishment and revision of MRLs.

#### Background

The Food Sanitation Law was amended and promulgated in May 2003. Based on the amended law, the Ministry of Health, Labour and Welfare (MHLW) is going to implement a positive list system for agricultural chemicals on/in food. The system is aimed at prohibiting the distribution of foods that contain agricultural chemicals above a certain level unless MRLs for the chemicals on/in the foods are established. This system will go into effect within three years after the publication of the amended Food Sanitation Law, May 30, 2003.

In the implementation of the positive list system, Japan expects foreign countries to make requests for establishing or revising MRLs for agricultural chemicals when these chemicals are newly approved in the countries for foods exported to Japan.

For agricultural chemicals used in Japan the MHLW establishes MRLs, based on Article 7 Paragraph 1 of the Food Sanitation Law, at the time of the registrations/authorizations of the agricultural by the Ministry of Agriculture, Forestry and Fisheries (MAFF).

#### II. Procedures for Establishment and Revision of MRLs for Agricultural Chemicals

##### 1. Application

Any person may apply to the Minister of Health, Labor and Welfare with Form 1 or 2 for the establishment or revision of MRLs for an agricultural chemical in the case that the chemical is approved in a country for foods exported to Japan. The Form should be accompanied by required documents on the chemical including data as described in the section III.

If the applicant is abroad, an appropriate contact person in Japan should be identified to handle the application. The Form should be submitted to the Standards and Evaluation Division, the Department of Food Safety, MHLW.